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REPLY

To: Examiner of the Patent Office

1. Identification of International Application  
PCT/JP03/15641

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4. Date of Notification: 19. 07. 2004

5. Subject Matter of Reply:

The reasons that the claimed invention is patentable will be described below.

1 Grounds for Amendments

Claims 1, 11, 12, 40, 45, 46, 51, 85, 96, 97, 98, 99, 100, 101, and 102 have been amended to specify that the claimed invention define by Claims 1-50 are directed to comprising collagen I, and Claims 51-102 are directed to comprising knit as the first layer and woven as the second

layer. Accordingly, claims 2-10, 52, 53 and 67 have been cancelled.

Therefore, the amendments raise no new matter issue.

## 2 Features of the Claimed Invention

As can be seen from the Amendments under Article 34 of PCT on the same date, a feature of the claimed invention is:

"A biocompatible implant, comprising: A) a biological molecule; and B) a support, wherein the biological molecule is type I collagen", (Claim 1).

Another feature of the claimed invention lies in

"A biocompatible tissue support, comprising: A) a first layer having a rough surface; and B) a second layer having a strength which allows the second layer to resist *in vivo* impact, wherein the first layer is attached to the second layer via at least one point[.], wherein the first layer is a knit, and wherein the second layer is a woven.", (Claim 51).

The present invention has a feature where the claimed biocompatible implant has a type I collagen, thereby attaining significant effects where an implant capable of being cellularized without self-reproducing material derived from organisms, such as a cell. By implanting the implant of the instant invention, an organ or tissue can be regenerated efficiently. By providing collagen I to the support, when the support is placed in organisms, cells aggregate to the support in the early period and subsequently the support itself is biologically degraded and eventually vanishes. Thereby, a graft which leaves

substantially no trace can be provided. (see, page 5, line 31 to page 6, line 3, Examples or the like).

Further, the present invention has a feature wherein the claimed biocompatible implant comprising a knit as the first layer, and a woven as the second layer. The combination of knit and woven also unexpectedly provides a material which has space for accommodating cells while preventing leakage and fray (see page 5, lines 28-30 of the PCT Description).

### 3 Subject Matter of Documents Cited in PCT Written Opinion

The Examiner cited D1-D14 as prior art references. However, none of the references reach or suggest the use of collagen I as a bio-molecule for biocompatible implants and the effects attained thereby, and the use of the combination of knit and woven as the first and the second layers for biocompatible implants and the effects attained thereby.

D1 teaches a bio-adsorbable stent graft. D1 fails to teach or suggest the use of collagen I as a specific biological molecule, and the use of the combination of a knit and a woven as the layers of a support. Therefore, D1 does not teach or suggest the claimed invention.

D2 teaches a vascular graft made of a knitted biostable polymer. D2 fails to teach or suggest the use of collagen I as a specific biological molecule, and the use of the combination of a knit and a woven as the layers of a support. Therefore, D2 does not teach or suggest the claimed invention.

D3 teaches a composite layered implant. D3 fails to teach or suggest the use of collagen I as a specific biological molecule, and the use of the combination of a knit and a woven as the layers of a support. Therefore, D3 does not teach or suggest the claimed invention.

D4 teaches a composite layered implant. D4 fails to teach or suggest the use of collagen I as a specific biological molecule, and the use of the combination of a knit and a woven as the layers of a support. Therefore, D4 does not teach or suggest the claimed invention.

D5 teaches a composite layered implant. D5 fails to teach or suggest the use of collagen I as a specific biological molecule, and the use of the combination of a knit and a woven as the layers of a support. Therefore, D5 does not teach or suggest the claimed invention.

D6 teaches a layered bone membrane for healing a recess. D6 fails to teach or suggest the use of collagen I as a specific biological molecule, and the use of the combination of a knit and a woven as the layers of a support. Therefore, D6 does not teach or suggest the claimed invention.

D7 teaches an implantable re-absorbable membrane. D7 fails to teach or suggest the use of collagen I as a specific biological molecule, and the use of the combination of a knit and a woven as the layers of a support. Therefore, D7 does not teach or suggest the claimed invention.

D8 teaches a connective tissue implant. D8 fails to teach or suggest the use of collagen I as a specific biological molecule, and the use of the combination of a knit and a woven as the layers of a support. Therefore, D8 does not teach or suggest the claimed invention.

D9 teaches a hernia mesh. D9 fails to teach or suggest the use of collagen I as a specific biological molecule, and the use of the combination of a knit and a woven as the layers of a support. Therefore, D9 does not teach or suggest the claimed invention.

D10 teaches a hernia membrane. D10 fails to teach or suggest the use of collagen I as a specific biological molecule, and the use of the combination of a knit and a woven as the layers of a support. Therefore, D10 does not teach or suggest the claimed invention.

D11 teaches a surgical plate. D11 fails to teach or suggest the use of collagen I as a specific biological molecule, and the use of the combination of a knit and a woven as the layers of a support. Therefore, D11 does not teach or suggest the claimed invention.

D12 teaches prosthesis for limiting postoperative adhesions. D12 fails to teach or suggest the use of collagen I as a specific biological molecule, and the use of the combination of a knit and a woven as the layers of a support. Therefore, D12 does not teach or suggest the claimed invention.

D13 teaches a implant made of three dimensional bio-absorbable collagen fiber. D13 fails to teach or suggest the use of collagen I as a specific biological molecule, and the use of the combination of a knit and a woven as the layers of a support. Therefore, D13 does not teach or suggest the claimed invention.

D14 teaches a prosthetic heart valve. D14 fails to teach or suggest the use of collagen I as a specific biological molecule, and the use of the combination of a knit and a woven as the layers of a support. Therefore, D14 does not teach or suggest the claimed invention.

#### 5.4 Comparison between the Claimed Invention and the Subject Matter of Documents

As described above, the claimed invention has a feature where the claimed biocompatible implant has a type I

collagen as well as the claimed biocompatible implant comprising a knit as the first layer, and a woven as the second layer.

On the other hand, none of Documents 1-14 describes or suggests a feature where the claimed biocompatible implant has a type I collagen, or a feature where the claimed biocompatible implant comprising a knit as the first layer, and a woven as the second layer.

Further, none of the cited references unexpectedly superior effects having either of the features as described above.

Accordingly, the claimed invention is not described or suggested in any of the documents cited. Therefore, in view of the state of the art as of the priority date of the present application, the claimed invention is not obvious over Documents 1-14 or any combination thereof.

Thus, the Applicant considers that there is no reason that the claimed invention lacks inventive step. The Applicant respectfully requests that the rejections of Point V. should be withdrawn and that the Examiner issue an International Preliminary Examination Report describing that all of the claims have novelty (N), inventive step (IS), and industrial applicability (IA).

Respectfully submitted